unit, or other appropriate personnel. Individual reports or a summary must be sent, along with recommended changes in laboratory procedure or policy, to the commander or institute director. Policy or procedural changes must be implemented if deemed necessary by the commander or institute director.

(3) Any mishaps with etiologic agents used under sponsorship of the BDP that result in sero-conversion or a laboratory-acquired illness will be reported.

§ 627.19 Large-scale operations.

(a) *Large-scale.* In addition to the requirements stated in § 627.13, the following applies to research or production activities involving viable etiologic agents in quantities greater than 10 liters:

(1) All large-scale operations will be conducted in facilities described in § 627.47.

(2) Cultures will be handled in a closed system.

(3) Sample collection, the addition of materials, and the transfer of culture fluids shall be done in a manner which minimizes the release of aerosols or contamination of exposed surfaces.

(4) A closed system or other primary containment equipment that has contained viable organisms shall not be opened for maintenance or other purposes unless it has been sterilized.

(5) SOPs will include a section describing and requiring a validation of the process equipment's proper function.

(6) Scientists, technicians, equipment workers, and support personnel with access to the large-scale production area during its operation will be included in the medical surveillance program.

(b) *BL–2—LS.* In addition to the requirements stated in §§ 627.19(a) and 627.14, the following procedures will be employed for BL–2—LS:

(1) Rotating seals and other mechanical devices directly associated with the closed system used for the propagation and growth of viable organisms shall be designed to prevent leakage or shall be fully enclosed in ventilated housings that are exhausted through filters which have efficiencies equivalent to HEPA filters or through other equivalent treatment devices.

(2) A closed system used for the propagation and growth of viable organisms and other primary containment equipment used to contain operations involving viable organisms shall include monitoring or sensing devices that monitor the integrity of containment during operations.

(3) Systems used to propagate and grow viable organisms shall be permanently identified. This identification shall be used in all records reflecting testing, operation, and maintenance and in all documentation relating to the use of this equipment.

(c) *BL–3—LS.* In addition to the requirements stated in §§ 627.19(a) and 617.14, the following procedures apply:

(1) Personnel entry into the controlled area shall be through the entry area specified in § 627.47(c)(1).

(2) Persons entering the controlled area shall exchange or cover their personal clothing with work garments such as jumpsuits, long sleeved laboratory coats, pants and shirts, head cover, and shoes or shoe covers. On exit from the controlled area, the work clothing may be stored in a locker separate from that used for personal clothing, or discarded for laundering. Clothing shall be decontaminated before laundering.

(3) Entry into the controlled area during periods when work is in progress shall be restricted to those persons required to meet program support needs.

(4) Prior to entry, all persons shall be informed of the operating practices, emergency procedures, and the nature of the work conducted.

(5) The universal biohazard sign shall be posted on entry doors to the controlled area and all internal doors. The sign posted on the entry doors to the controlled area shall include a statement of agents in use and personnel authorized to enter.

(6) Equipment and materials required for the management of accidents involving viable organisms shall be available in the controlled area.

(d) *BL–4—LS.* Guidelines for these operations are not established. If these are needed, they must be established by the United States Army Surgeon

General or the NIH on an individual basis.

§627.20 Operations with radioactive material.

Operations that combine etiologic agents with radioactive material present unique problems. When this is the case, the following apply:

(a) *Radiation program.* A radiation program meeting the requirements of AR 385–11 and NRC licensing that allows the particular isotope and its use are required. The requirements for acquisition, handling procedures, labeling, storage, training, monitoring, and disposal will be described in an organization policy document.

(b) *Procedure approval.* In addition to the required approvals for work with etiologic agents, the RPO will approve all SOPs involving the use of radioactive materials. Laboratory operators must be fully trained, with annual training updates as required by the existing license.

(c) *Special situations.* (1) The laboratory waste must be segregated as radioactive waste and disposed of as such after it has been decontaminated. Do not mix nonradioactive waste with radioactive waste as the disposal of radioactive waste is much more complex and expensive. When RCRA-listed chemicals are mixed with radioactive waste, it becomes ''mixed waste'' for which there is currently no means of disposal.

(2) Activities conducted with radioisotopes should be confined to the smallest number of areas or rooms consistent with requirements.

(3) Decontamination methods specific to etiologic agents will not always remove radioactivity. Other methods, such as specialized detergents and solvents designed for this use, should be employed to remove residual radioactivity.

Subpart D—Personal Protective Equipment

§627.21 Introduction.

Personal protective equipment (PPE) includes clothing and equipment used to protect the laboratory worker from contact with infectious, toxic, and corrosive agents, as well as excessive heat, fire, and other physical hazards. The appropriate PPE for any activity depends upon the proposed operations and the potential hazards associated with them. While PPE is an important item of personal protection, it serves as only a secondary line of protection against hazards in the workplace. Engineering controls (subpart H), combined with common sense, good laboratory techniques, and adherence to SOPs, are the primary barriers to exposure. There are some situations, however, in which it is either impractical or impossible to rely exclusively on engineering controls. In these cases, PPE may form the primary barrier between personnel and the hazardous or infectious materials.

§627.22 Minimum laboratory attire for use of etiologic agents.

Individuals required to wear PPE will be trained in its proper use. The PPE listed below is the minimum required when etiologic agents are handled at any biosafety level. Research with etiologic agents usually involves hazards other than those presented by the agents themselves. When PPE is selected, the hazards presented by these other factors must be considered regardless of the biosafety level used. For example, toxic chemicals are commonly used in research involving etiologic agents. The processes may expose personnel to physical hazards, such as heat or animal bites, and the decontamination process may involve the handling of toxic or corrosive materials. When the PPE required to mitigate these hazards exceeds that of the minimum requirements, the necessary PPE will be selected considering all the hazards. Information regarding the additional appropriate PPE worn to protect against these hazards will be available from one of the following sources: MSDS, SOP for the operation, or the safety officer. Deviations from the standards stated in approved SOPs must be approved by the safety officer. All laboratory coats worn to protect the individual should be left in the laboratory when that individual leaves. In each case, the minimum attire will be—

(a) *Laboratory workers.* Street attire is permissible in the laboratory, but